

IN THE UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF TENNESSEE  
NASHVILLE DIVISION

IN RE:	)	
	)	
AREDIA <sup>®</sup> and ZOMETA <sup>®</sup> PRODUCTS	)	No. 3:06-MDL-01760
LIABILITY LITIGATION	)	Judge Campbell
	)	Magistrate Judge Brown
This Document Relates to All Cases	)	

**PLAINTIFFS' STEERING COMMITTEE'S  
MOTION TO COMPEL NOVARTIS DISCOVERY RESPONSES**

In compliance with the Court's order of December 22, 2006, the Plaintiffs in the above action file this Motion to Compel Discovery Responses from defendant Novartis Pharmaceuticals Corporation ("Defendant" or "Novartis").

Plaintiffs ask the Court to order Novartis to provide responsive information to a number of discovery requests and to correct deficiencies which Plaintiffs have not been able to resolve by agreement with counsel for Novartis.

As noted in the recent telephone conference with the Court, all but a few of these items are being brought to the Court's attention after weeks of correspondence and negotiation between counsel for the parties. Others have been the subject of more recent discussions. For the Court's reference, the key documents underlying Plaintiffs' requests for relief are as follows:

- Novartis Pharmaceuticals Corporation's Second Supplemental Responses to Plaintiffs' First Set of Interrogatories ("Novartis Interrogatory Responses"), attached as Exhibit 1 (filed under seal).
- Novartis Pharmaceuticals Corporation's First Supplemental Objections and Responses to Plaintiffs' First Request for Production, ("Novartis Response to Document Requests") attached as Exhibit 2 (filed under seal).
- Plaintiffs' Counsel's First Letter Regarding Discovery, Valad 09/08/2006 Letter to Latimer, attached as Exhibit 3.

- Novartis's First Letter Regarding Discovery, Latimer Letter to Valad 09/26/2006, attached as Exhibit 4.
- Plaintiffs' Counsel's Second Letter Regarding Discovery, Valad 12/04/2006 Letter to Latimer, attached as Exhibit 5.
- Plaintiffs' Counsel's Third Letter Regarding Discovery ("Pellechio Deposition"), Valad 12/04/2006 Letter to Latimer, attached as Exhibit 6.
- Plaintiffs' Counsel's Fourth Letter Regarding Discovery ("Data Problems in Production"), Valad 12/06/2006 Letter to Latimer, attached as Exhibit 7.
- Novartis's Response to Second Letter Regarding Discovery, Latimer 12/11/2006 Letter to Valad, attached as Exhibit 8.
- Novartis's Response to Third Letter Regarding Discovery (Response re: "Pellechio Deposition"), Latimer 12/11/2006 Letter to Valad, attached as Exhibit 9.
- Novartis's Response to Fourth Letter Regarding Discovery (Response to "Data Problems in Production"), Latimer 12/11/2006 Letter to Valad, attached as Exhibit 10.
- Plaintiffs' Counsel's Fifth Letter Regarding Discovery ("Hoffman Deposition"), Beatie 12/15/2006 Letter to the Court, attached as Exhibit 11.
- Plaintiffs' Counsel's Sixth Letter Regarding Discovery, Valad 01/02/2007 Letter to the Latimer, attached as Exhibit 12.

Plaintiffs' counsel are cognizant of the Court's instruction at the December 18, 2006 telephonic conference to bring disputes to the Court's attention earlier in the process, and this directive by the Court shall guide Plaintiffs' future conduct.

Plaintiffs seek relief on the following issues.

### **Improper Redactions**

In its review of documents so far, Plaintiffs have seen myriad documents containing improper redactions. In some cases, the redactions remove all or almost all of the information on the page, rendering the document useless. See examples attached hereto as Exhibits 13, 14, and 15 (all submitted under seal). Exhibit 13 has a heading indicating that the document appears likely to be of interest to Plaintiffs, but the entire body of the document is redacted. It is clear from the e-mail that is adjacent to Exhibit 14 in the production that Exhibit 14 is an organizational chart of a Novartis business unit, but it too is entirely "blacked out" with a redaction that covers the entire multi-page

document. Exhibit 15 appears to be a document submitted to Novartis by a third party, but the names of the person(s) have been redacted. Often, as is the case with all three of these examples, *there is no information in the privilege log regarding the redactions.* The number of such documents containing redactions not noted in the privilege log runs into the tens of thousands.

It is plainly improper for Novartis to redact information from a responsive document without any explanation. It is Novartis's burden to provide a privilege log that contains the necessary information. It is Novartis's obligation to refrain from making unjustified and unsupportable redactions on responsive documents. Plaintiffs ask the Court to order Novartis to reproduce in unredacted form every document not listed on the privilege log, and to provide an updated and complete privilege log every time new documents are produced.

**Novartis's Refusal to Specify What is Being Produced and What is Being Withheld**

Based on the form of Novartis's responses it is impossible for Plaintiffs to determine what Novartis has agreed to produce and what they are withholding from the production on the basis of their copious objections. For example, its discovery responses begin with a five page "Preliminary Statement" and a six page "Document Production Protocol" which are in substance a long list of general objections to Plaintiffs' discovery requests (which, in addition are incorporated into specific objections). See Novartis Response to Document Requests, at p. 11, Exhibit 2.

This Court has cautioned the parties about invoking boilerplate or standardized objections. Novartis has gone one step further, setting forth a "speaking" objection, replete with qualifications, disclaimers and parameters that make it absolutely impossible to determine if any documents produced represent all of the documents responsive to a particular request.

In addition, many specific responses to individual requests are made "subject to" a long list

of objections, further masking whether the answers are in fact substantive and complete. For example, Novartis's response to Interrogatory number 12, at the bottom of page 24, states that Novartis's answer "is made subject to and without waiving objections 1, 3, 4, 5, and 6, which are incorporated by reference." (Novartis Interrogatory Responses, at 24, Exhibit 1.) A reference back to pages 2-5 of the Responses is required to recognize that Novartis's response is subject to a laundry-list of objections that are too numerous to list here, and are, except for attorney-client privilege, insufficient to withhold documents. Given the myriad objections, how can Plaintiffs understand the scope and completeness of the responses? Of course, they cannot.

Plaintiffs ask the Court to strike Novartis's objections (including its Preliminary Statement) or order Novartis to identify with specificity, those objections that pertain to a particular request. Further, Plaintiffs ask the Court to order Novartis to provide all documents and information that are responsive to Plaintiffs' discovery requests and to require Novartis to withdraw its Preliminary Statement, and to identify,

**Watermark Obscuring Document Text**

As discussed in the December 18, 2006 telephonic conference with the Court, *every page* of the document production by Novartis is stamped diagonally from the upper left corner to the bottom right corner with a legend that is *eight inches long and more than an inch and one-half high* that says "MDL." See the examples attached as Exhibits 16, 17, and 18 (all submitted under seal). This obscures the text on every document produced by Novartis, in violation of the Case Management Order, and makes the review of the millions of pages of documents being produced in this litigation far more difficult than necessary because the reader must "look around" the large, obscuring "MDL" watermark stamped across the page. Additionally, it prevents Plaintiffs from performing their own

optical character recognition or “OCR” as needed on the documents Novartis is producing. One of Plaintiffs’ technology consultants working on Novartis’s document production has indicated to Plaintiffs that there are a number of documents where he would like to reproduce the OCR provided by Novartis, to determine if higher quality can be obtained, but this is not possible given the “MDL” watermark obscuring the text of the documents. And finally, the watermark is wholly unnecessary, as Defendant has placed a legend and bates number at the bottom of every page that does not obscure the text and that completely suffices to identify the source of the document.

Plaintiffs ask the Court to order Novartis to reproduce the documents produced so far without the obscuring watermark (the Court has already ordered Novartis to do so with regard to documents produced after December 18, 2006). One of Plaintiffs’ technology consultants advises Plaintiffs that the documents can be reproduced in an automated fashion without the watermark at minimal cost using the automated capabilities required to produce the documents with the obscuring watermark in the first instance. (Declaration of Keith Altman ¶ 22, Exhibit 19.) Plaintiffs’ technology expert further explains that even without prior specific knowledge of Novartis’s files, he could perform the work to reproduce the documents without the obscuring watermark in eight to sixteen hours. (Altman Declaration ¶ 23, Exhibit 19.)

#### **Failure to Provide Initial Disclosures - “Core” and “Fifty” Employees**

Novartis’s Preliminary Statement refers to collecting documents from “Core” and “Fifty” employees. The “Core” employees are apparently the fifteen persons identified by Novartis from whom they are also collecting responsive e-mails. Through a series of letters to Novartis’s counsel, Plaintiffs have been able to establish that the “Fifty” employees is, apparently, in actuality seventy persons, not “fifty,” notwithstanding Novartis’s continuing to reference these persons as the “Fifty

Employees.” (*See* Letter from Robert Johnston dated December 12, 2006, attached as Exhibit 20.)

The letter from Novartis’s counsel listing the seventy persons (plus Archives) does not include any information as to the persons’ job titles, positions, or duties.

This defect in Novartis’s responses flows in part from Novartis’s failure to fully answer required Initial Disclosure number (1)(a) under Rule 26(a), where Defendant was required to identify persons having discoverable information in the case. The letter listing the seventy persons was Novartis’s incomplete effort—months late and after multiple requests by Plaintiffs—to provide the information it was required to provide under Initial Disclosure number (1)(a). Plaintiffs do not know if the seventy people Novartis erroneously counts as “fifty” is in fact the complete list, or if there will be other unaccounted for additions in the future. The fact that the number is seventy and not “fifty” underscores that Novartis has not met its duty to provide Plaintiffs with specific, identifying information about the persons who have discoverable information in this case. Plaintiffs ask the Court to order Novartis to comply with Initial Disclosure number (1)(a) and fully identify the persons having discoverable information in the case.

The question of the identity of persons having information regarding the claims was also addressed to Defendant via Plaintiffs’ interrogatories (numbers 27 and 28). (*See* Novartis Interrogatory Responses at p. 34-35, Exhibit 1 (filed under seal)). These interrogatories ask Novartis to identify persons who have information regarding Plaintiffs’ complaint, and to specify the subject matter which each identified person possesses. Defendant has refused to fully answer these interrogatories. Plaintiffs ask the Court to order Novartis to fully comply with its Initial Disclosure obligations, and to fully answer interrogatory numbers 27 and 28.

### **Identities of Non-Novartis Employee Professionals**

In its discovery responses, Novartis has refused to produce the names of non-Novartis professionals doing work in connection with the drugs Aredia<sup>®</sup> and Zometa<sup>®</sup>. Plainly, these third parties—who are beyond Novartis’s control—will have a wealth of information about what went on in the clinical trials, efforts to discover the causal link between Aredia<sup>®</sup> and Zometa<sup>®</sup> and osteonecrosis of the jaw, etc., all of which is relevant to this litigation. Initially, Novartis objected on the basis that the information was allegedly shielded under the Code of Federal Regulations. When Plaintiffs pointed out, in two separate letters to Novartis’s counsel beginning on September 8, 2006, that the identities of these persons are not shielded by the C.F.R., Novartis abandoned its unsupportable legal objection and shifted its ground, stating in a recent letter *more than three months after Plaintiffs’ first letter* that it would not unconditionally produce the information because Novartis “believes it has the obligation to protect the names of non-Novartis professionals who have worked on Zometa<sup>®</sup> and Aredia<sup>®</sup> based on matters of privacy and based on [Novartis’s] duty to avoid the chilling effect on future work that revealing these names would have should these individuals become involved in litigation.” (Latimer 12/11/2006 Letter to Valad, pp. 2-3, Exhibit 8.)

Novartis then proceeds to offer, *conditionally*, to provide *part* of the information sought, saying that “Nonetheless, [Novartis] is willing to provide unredacted copies of the documents containing such names in the NDAs for Zometa<sup>®</sup> and Aredia<sup>®</sup> if plaintiffs are willing to agree to a few conditions . . . .” (Latimer 12/11/2006 Letter to Valad, p. 3, Exhibit 8.) This is unacceptable. Novartis has no legal basis for withholding the names; there is no basis for providing some names (within the context of the NDAs) while withholding others; and there is no basis for demanding concessions and “conditions” in exchange for providing responsive, non-privileged information.

Plaintiffs ask the Court to order Novartis to produce copies of all documents with the names of non-employee professionals working on Aredia® or Zometa® unredacted.

**Referring Plaintiffs to Document Production In Lieu of Written Answers to Interrogatories**

In a number of instances, Defendant refers Plaintiffs to the six million pages of documents that it expects to produce to find an answer to an interrogatory question. For example, in response to interrogatory number 11, which seeks the identities of persons supervising the testing of the drugs, Novartis states:

The individuals listed in the document production protocol may have responsive knowledge. To the extent that [Novartis] may have additional information, [Novartis] refers plaintiffs, pursuant to Fed. R. Civ. P. 33(d), to documents that will be made available to plaintiffs (as set forth in the Document Production Protocol)—including but not limited to, the NDAs for Aredia® and Zometa® and documents collected from the following custodial sources: Diane Young, Robert Spaet, Nicholas Sauter, and Peter Tarasoff. The burden of reviewing these documents is the same for plaintiffs as it is for [Novartis].

(Novartis Interrogatory Responses at 23, Exhibit 1.)

Novartis's answer is non-responsive. First, references to the six million page document production without specifying narrow, discrete, specific bates number ranges, does not satisfy Novartis's discovery obligations. Rather, telling Plaintiffs to look through six million pages of documents to find an answer is merely an attempt by Novartis to avoid answering the question. In addition, the response is facially insufficient as Novartis has not yet completed its production of documents to Plaintiffs, despite the fact that discovery has been proceeding for over six months. Novartis's response would require Plaintiffs to re-examine documents to verify interrogatory "answers" every time Novartis produces another part of the rolling production.

Plaintiffs ask the Court to order Novartis to answer all interrogatories with sworn, written, responsive answers, and only to refer to documents in lieu of written responses when there are a



reasonable number of discrete, responsive documents that fully answer the question and Defendant directs Plaintiffs to these documents by identifying the exact bates numbers, and not by vague references to large numbers of documents.

**Identity of Persons Supervising the Testing of Aredia<sup>®</sup> and Zometa<sup>®</sup>**

Novartis has refused to identify the persons supervising the testing of the drugs. As explained above, this information was initially sought by Plaintiffs through interrogatories served early in 2006, prior to the formation of the MDL. This question was also insufficiently answered in Novartis's recent 30(b)(6) deposition, as described to the Court in the December 18, 2006 telephonic status conference. Novartis's refusal to answer the interrogatory is, in Novartis's counsel's most recent correspondence, based on the assertion that Plaintiffs can find this information by looking through the several million pages of documents Novartis is producing (despite, of course, the fact that the production is not complete). Latimer 12/11/2006 Letter to Valad at 3-4, Exhibit 8. Since the December 18 telephonic conference with the Court, counsel for Novartis has offered to send a list of persons working on the testing of the drugs, then to discuss whether they will agree to proffer another 30(b)(6) witness who can actually answer the questions regarding supervision of the testing.

As referenced above, Novartis cannot satisfy its discovery obligations by instructing Plaintiffs to look through six million pages of documents to find the answer to the simple, direct, straightforward, and highly relevant question of the identities of the persons supervising the clinical trials of the drugs, and by failing to designate a 30(b)(6) witness who can respond to the question. Plaintiffs ask the Court to order Novartis to fully respond to this interrogatory, and to fully identify those persons by name, title(s), time period in the position(s), and roles in the clinical trials. Plaintiffs also ask the Court to order Novartis to reconvene the 30(b)(6) deposition, and to designate

a witness who can substantively respond to the questions. In the alternative, Plaintiffs ask the Court to enter an order stating that Novartis's recordkeeping is incomplete and that Novartis has no record of who, if anyone, supervised the testing of the drugs.

**Interrogatory Number 12 – Testing Performed on the Drugs**

This interrogatory asks Novartis for a description of all testing done on the drugs. Again Novartis refuses to answer, stating that Plaintiffs can determine the answer by reviewing the six million documents scheduled to be produced. For the reasons stated previously, this answer does not satisfy Novartis's discovery obligations. Plaintiffs ask the Court to order Novartis to fully respond to this interrogatory.

**Interrogatory Number 13 – Identities of Dentists / Oral Cavity Specialists Participating in Testing.**

This interrogatory asks Novartis to identify all dentists or oral cavity specialists who participated in the testing of the drugs. Novartis refuses to answer, and again instructs Plaintiffs to review the six million documents being produced to find the answer. Plaintiffs believe, based on information developed in the case so far, that no dentists or oral cavity specialists participated in the testing of the drugs, which is one of the ways in which Novartis was negligent in failing to warn doctors and patients of the risk of developing osteonecrosis of the jaw when using Novartis's drugs. Plaintiffs ask the Court to order Novartis to fully respond to this interrogatory with the name, addresses, date of participation and manner of participation of each such professional. In the alternative, Plaintiffs ask this Court to enter an order stating that no dentists or oral cavity specialists participated in the trials of the drugs, and prohibiting Novartis from introducing any such evidence, to the extent it later turns up, at trial.

**Interrogatory Number 16 – Identity of Consultants Researching the Safety of the Drugs**

This interrogatory asks Novartis to identify consultants researching the safety, effectiveness, or potential side effects from or adverse reactions to the drugs. Novartis again refers Plaintiffs to the incomplete production of six million documents to decipher the answer. For all the reasons described above, Plaintiffs ask the Court to order Novartis to fully respond to this interrogatory, or, in the alternative, enter an order to the effect that no such persons exist.

**Interrogatory Number 19 – Studies Regarding Causal Connection to ONJ**

This interrogatory asks Novartis to describe studies that have been done regarding a causal connection between the use of the drugs and ONJ. Novartis states that it has designed and is in the process of designing studies and prospective trials, but offers no specifics or details. Plaintiffs ask the Court to order Novartis to fully respond to this interrogatory.

**Interrogatory Number 26 – Other Lawsuits Concerning the Drugs**

This interrogatory asks Novartis to identify other lawsuits concerning the drugs. Novartis's response simply stated that Plaintiffs know about the suits that Plaintiffs themselves filed. This is, of course, non-responsive to the question, as Plaintiffs seek only information about other cases concerning the drugs, not identification of their own lawsuits. Plaintiffs ask the Court to order Novartis to fully respond to this interrogatory.

**Document Request Number 10 – Correspondence Relating to the Drugs**

Plaintiffs seek in this request copies of all correspondence regarding the drugs with any government entity, whether foreign or domestic. Novartis, in its responses, initially stated it would produce correspondence with the FDA, and refused to produce correspondence with any other agency or government. In the letter from Novartis's counsel dated December 11, 2006 attached as

Exhibit 8, Novartis now states that it typically does not correspond with foreign agencies, and that to the extent it did, the correspondence would be sprinkled through the files of various employees being produced in the six million page document production.

The complete inconsistency in these two positions leaves Plaintiffs without any way to understand which answer, if either, is correct. Further, it appears to Plaintiffs that there is some likelihood that when Novartis says it does not typically correspond with foreign governments that what is really being said is that *other Novartis sister companies or Novartis's corporate parent* typically handle correspondence with other governments. Plaintiffs ask the Court to order Novartis to produce correspondence between any corporate affiliate or parent of Novartis and any foreign government or agency regarding the drugs. Further, defendant should produce them in a way that does not require a review of various portions of the six million page production, by designating the specific bates ranges where these documents can be found or by otherwise identifying them.

#### **Document Requests 35 and 36 – Novartis Sales and Profits**

These document requests seek financial statements of Defendant, and revenue and profit information from sales of the drugs that are placed directly at issue in the case as a result of the Plaintiffs' punitive damages claims, and indeed as motive for Novartis's behavior in the sale and promotion of the drugs in question. These requests are also relevant to the Plaintiffs' forthcoming request for class certification. Novartis claims discovery of this information is "premature," and refuses to produce it. Novartis cannot unilaterally decide when it will respond to discovery requests. Plaintiffs ask the Court to order Novartis to produce the requested information.

### **Index of Documents Being Produced**

For files and electronic documents being produced from individual custodians, Novartis has provided no index to the information being produced. For example, Novartis will produce a batch of documents in which it identifies the name of the custodian who is the source of the information, but it does not provide an index as to the content of the hard copy files or electronic files being produced from that person. (Plaintiffs agree that an “index” to individual e-mails would be burdensome for defendant to produce, and accordingly have never sought and do not seek such an index.)

Novartis claims that no such index information for the files of the individual custodians exists. However, counsel for Novartis collected the information being produced, and it is counsel’s obligation to provide it to Plaintiffs organized by the request to which it responds or in the manner in which it was kept. The files were obviously kept by the individual custodians with identifying or indexing information (i.e., “correspondence,” “R&D,” “adverse events”) sufficient to maintain basic organization of the information. Novartis is obligated to transmit this information to Plaintiffs, and it is not sufficient merely to assert that Plaintiffs do not need this information because they have the ability to perform certain electronic searches of the information. There is no electronic search that can be done that will identify the contents of the files being produced. Plaintiffs ask the Court to order Novartis to produce index information sufficient to identify the contents of the individual custodians’ files that are being produced.

### **Incomplete Information Required to Meaningfully Search Documents**

Compounding the problems caused by a lack of an index to the files, Novartis has produced the images of the e-mails and other electronic documents in such a way as to severely restrict the usability and retrievability of the information. Certain identifying information is easily extracted at

the time that electronic documents and e-mails are converted to images, and easily provided as separate fields. The processes for doing this are automated and routinely performed in large litigation document productions. Obviously, in a case in which millions of documents have to be reviewed, the ability to retrieve and manipulate such documents easily and quickly is critical.

The identifying information that was not separately extracted and provided in Novartis's e-mail production is:

- Date sent
- Date received
- Author/sender (to include not only screen name / alias, but also actual e-mail address)
- Recipients (to include not only screen name / alias, but also actual e-mail address)
- Carbon copy recipients (to include not only screen name / alias, but also actual e-mail address)
- Blind carbon copy recipients (to include not only screen name / alias, but also actual e-mail address)
- Title of document (i.e., e-mail subject)<sup>1</sup>

Similarly, the following identifying information was not separately extracted and provided in Novartis's production of non-email electronic documents is:

- Document type
- Date created
- Date last revised
- Author
- Title of document
- Original path where document was located
- Original file name of document

This does not mean that Plaintiffs cannot see the information above. What it means is that Plaintiffs cannot search the documents utilizing the various fields. For example, Novartis can conduct a

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<sup>1</sup> Defendant initially produced e-mails without sufficient information to logically link e-mails with their associated attachment(s), beyond making them contiguous in the production. By letter dated December 11, 2006 attached as Exhibit 11, counsel for Novartis has agreed to supply this missing information, thereby hopefully obviating the need for the Court to order relief on this point.

search in such a way as to retrieve all of the e-mails sent by a particular employee in January 2005. Plaintiffs, on the other hand, can only search for all documents that mention the particular employee, and then manually scour those documents, which could number in the hundreds or thousands, to find e-mails transmitted in January 2005.

Novartis, in correspondence with Plaintiffs' counsel states, that it is "already" providing this information by providing the full text image of the documents being produced. This is not responsive to the question posed by Plaintiffs, and is misleading. Absent production of the missing information, Plaintiffs will not be able to search for and retrieve documents by date, by author, etc. In the routine course of their business, Novartis has the data that Plaintiffs request above, and has the ability to use it to locate and retrieve information. (Altman Decl. ¶¶ 15-17, Exhibit 19.) In effect, they have created an uneven "playing field," where they can more easily retrieve information regarding the documents involved in the litigation than can the Plaintiffs. (Altman Decl. ¶¶ 17, Exhibit 19.)

Plaintiffs ask the Court to order Novartis to produce the above-listed identifying information for all e-mails and other electronic documents being produced in this litigation.

#### **Missing Items in Production**

At Defendant's request and in follow-up to correspondence between the parties in December, Plaintiffs, on December 29, 2006, provided to Defendant (i) lists of bates number "gaps" in the production, (ii) records missing identifying information that was correctly provided with other documents of the same type in the production, and (iii) images that were provided without OCR or extracted text information. It is Plaintiffs' hope that the parties will be able to resolve these issues by agreement prior to the hearing on this matter. Should the parties not be able to agree, Plaintiffs

ask the Court to order Novartis to produce the missing information.

**Anderson Clinic Study Data**

On February 22, 2006, counsel for Novartis provided to Plaintiffs partial results of a retrospective study of M.D. Anderson patients being treated with intravenous bisphosphonates. Plaintiffs understand that Novartis has commissioned or is funding this analysis. By letter dated October 3, 2006, counsel for the Plaintiffs asked for updated information regarding the study. No response has been provided by Novartis as of this time. Plaintiffs ask the Court to Order Novartis to provide updated results for the M.D. Anderson study as they are available.

**Completion Date For Document Production**

At the conclusion of the initial conference with the Court in this matter on June 29, 2006, Plaintiffs understood that Novartis would be producing documents on a rolling basis, but that the entire production would be completed in a matter of a few weeks or months. More than six months after that conference, Defendant has produced only about 60% of the documents that Novartis has stated that it intends to produce, notwithstanding the incomplete items and items missing from the production so far.

To date, Plaintiffs have no idea as to when Novartis intends to complete its document production. Plainly, Plaintiffs' ability to undertake depositions of Novartis witnesses is severely hampered by the incomplete nature of the production to date, as for most witnesses extensive and complete review of the documents must be performed prior to their depositions. The delay in providing documents redounds to the benefit of the Defendant, and prejudice to the Plaintiffs, as Defendant in this matter has every incentive to delay as long as possible. Novartis is a multi-billion dollar corporation, with assets and resources that enable it to complete this type of document



production in a matter of weeks. Plaintiffs ask the Court to order Novartis to complete the production of documents within the next forty-five days.

**Proffer of Witnesses Unable to Answer Questions at 30(b)(6) Depositions**

Novartis designated two witnesses to testify in response to 30(b)(6) deposition notices, neither of whom was able to fully and completely answer questions regarding the topics set forth in the notices. As explained in the December 18, 2006 telephonic conference with the Court, this happened with regard to the deposition of Novartis's employee Dr. Hoffman, and previously with regard to Novartis employee Mr. Pellechio. (See Plaintiffs' Counsel's Letters attached hereto as Exhibits 6 and 11.)

Novartis has, as of this writing, had its counsel provide written answers to some, but not all, of the questions that Mr. Pellechio could not answer, and proposes to do the same with Dr. Hoffman. Novartis has asserted in conversations with Plaintiffs' counsel that the supplementing of incomplete deposition testimony with letters from counsel is a cure for the improper designation of a witness, and obviates the need for further testimony from these witnesses. Novartis's approach would, at Defendant's unilateral discretion, result in the substitution of letters from counsel for the sworn testimony of witnesses with first hand information regarding the facts. Obviously, this approach is prejudicial to the Plaintiffs, as "lawyer talk" is not a substitute for sworn testimony that is binding on the Defendant. This is especially so when Defendant has provided patently unqualified and unprepared 30(b)(6) witnesses. Plaintiffs have notified Defendant of the inappropriateness of this approach by letter dated January 2, 2007. Valad 01/02/2007 Letter to the Latimer, attached as Exhibit 12.

Plaintiffs ask the Court to order the designation of new witnesses to answer the questions left

unanswered by the testimony of Mr. Pellechio and Dr. Hoffman, and to order Novartis to designate fully qualified witnesses in the future upon penalty of sanction should Novartis fail to do so.

**Designation of Documents as Confidential**

One new issue became apparent to Plaintiffs in the preparation of this motion. The Protective Order entered in this case permits the parties to invoke the Order's confidentiality provisions by marking documents and other evidence as "Confidential" or "Subject to Protective Order." It appears to Plaintiffs that every document produced by Defendant so far is marked with the legend "PRODUCED PURSUANT TO PROTECTIVE ORDER ENTERED IN CASE 3:06-MD-1760 (MD TENN)." No other confidentiality legend or stamp is applied to any documents reviewed by Plaintiffs to date. Accordingly, it appears that Novartis asserts that every document it produces to Plaintiffs is subject to the confidentiality provisions of the Protective Order, requiring Plaintiffs to file them under seal when they are presented to the Court, even if the document is devoid of any substance or came from a third party. Indeed, Novartis marked with this confidentiality legend articles written by third parties that have been published in medical or dental journals. (See article entitled "Osteonecrosis of the Jaws Associated With the Use of Bisphosphonates: A Review of 63 Cases," Salvatore L. Ruggiero, DMD, MD, Chief, Division of Oral and Maxillofacial Surgery, Long Island Jewish Medical Center, New Hyde Park, NY, © 2004 American Association of Oral and Maxillofacial Surgeons, Exhibit 21 (filed under seal)).

Because Novartis marked this published article with the confidentiality legend, Plaintiffs had to file a copy of it under seal in order to avoid violating the terms of the Protective Order. Likewise, Plaintiffs had to file under seal the copies of the documents where all substantive information on the document was redacted. This is an unnecessary and unjustified burden. Plaintiffs ask the Court to

order Novartis to remove the confidentiality legend from any document where Novartis does not have a legitimate interest in confidentiality. Absent this relief, Plaintiffs and the Court will be burdened by the requirement of repeatedly filing documents under seal.

### **Plaintiffs' Interrogatories**

The Case Management Order states that no further interrogatories may be propounded on Defendant without leave of the Court or agreement of the parties. Accordingly, Plaintiffs have not been able to propound any interrogatories on Defendant since the formation of the MDL. As demonstrated by the numerous issues and questions referenced in this motion, Plaintiffs have a number of areas of inquiry where additional interrogatories would be of assistance. Plaintiffs have recently sought the agreement of the Defendant for Plaintiffs to serve 25 additional interrogatories. (Valad Letter 01/04/2007 to Latimer, attached as Exhibit 22.) Plaintiffs hope that Defendant will agree to this request. Absent Defendant's consent, Plaintiffs ask the Court to enter an order allowing Plaintiffs to serve 25 interrogatories.

WHEREFORE, PREMISES CONSIDERED, the Plaintiffs' Steering Committee asks the Court to order the discovery and other relief requested herein.

Respectfully submitted,

PLAINTIFFS' STEERING COMMITTEE

BY: /s/ Bart T. Valad

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Dated: January 5, 2007

**CERTIFICATE OF SERVICE**

I hereby certify that a copy of the foregoing was served on January 5, 2007 by operation of the Court's Electronic Case Filing System, on counsel of record in case No. 3:06-MD-1760.

/s/ Bart T. Valad

Bart T. Valad